

REMARKS

Claims 20-47 are pending in the application. Claims 1-19 have been canceled without prejudice to refilling the claims in a divisional application. Claims 45-47 are newly added herein. Claims 20, 30, 44, and 45 are the only independent claims.

Claims Rejections - 35 U.S.C. § 103

Claims 20-44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,343,731 to Adams et al. ("Adams") in view of U.S. Patent No. 4,577,787 to Leisenring.

Applicant respectfully traverses the rejection of claims 20-44 for reasons set forth below. Applicant accordingly requests reconsideration of claims 20-44.

Independent Claim 20 As set forth in claim 20, a method for the treatment of hemorrhoids, in accordance with the present invention, utilizes an anoscope and a hemorrhoid occlusion device. The anoscope includes a hollow body having a sidewall provided with a window, while the hemorrhoid occlusion device has a distal end provided with a pair of jaws, at least one of the jaws including a C- or U-shaped clamping member. The method includes (i) inserting the anoscope into an anal canal, (ii) manipulating the anoscope so that hemorrhoidal tissues protrude through the window into the anoscope, (iii) inserting the jaws of the occlusion device into the anoscope, (iv) manipulating the occlusion device, after the protruding of the hemorrhoidal tissues through the window and after the inserting of the jaws into the anoscope, so that the jaws are located on opposite sides of the hemorrhoidal tissues, (v) thereafter closing the jaws to clamp the hemorrhoidal tissues, and (vi) subsequently operating a tissue occlusion component of the occlusion device to permanently constrict a portion of the hemorrhoidal tissues.

The Adams reference discloses a full-thickness resection system comprising a flexible endoscope and a stapling mechanism, wherein the endoscope is slidably received through at least a portion of the stapling mechanism. The flexible endoscope includes an

elongate flexible shaft for insertion, with the stapling mechanism, into a tubular internal organ such as the colon to assist in repairing the organ after resection of a portion thereof.

Leisenring discloses a rectal speculum, a short rigid tubular member, closed at a distal end for insertion into the rectum. The speculum of Leisenring is used to perform medical procedures on the rectal portion of the colon under direct observation.

Applicant respectfully asserts that one of ordinary skill in the art would not be motivated by the prior art to use the resection system of Adams with the Leisenring speculum. First, the Adams resection system is designed to be used in combination with a flexible endoscope and there is no need to insert an endoscope into the Leisenring speculum during a medical procedure. Moreover, one of ordinary skill in the art would not consider using the stapling device of the Adams resection system apart from a flexible endoscope.

Neither Adams nor Leisenring provides any motivation or suggestion to one of ordinary skill in the art to use the stapling mechanism of Adams without a flexible endoscope. Using the Adams resection system with the Leisenring speculum would be awkward or difficult, if not impossible, and is certainly not within the ordinary artisan's range of skills. An elongate flexible endoscope would be an obstacle to proper work on hemorrhoids. In order to enable the use of the stapling device without the endoscope and with the Leisenring speculum would require a redesign of the instrument that is beyond the abilities and inclinations of one of ordinary skill in the art.

In brief, neither Adams nor Leisenring provides any motivation or suggestion to one of ordinary skill in the art that the Adams stapling device could be used, with or without an endoscope, with the Leisenring speculum. It is only applicant's disclosure that provides the insight and invention enabling the Examiner to combine the Adams and Leisenring teachings.

Accordingly, applicant requests reconsideration of the rejection of claim 20.

Independent Claim 30 As set forth in claim 30, a surgical instrument assembly for the treatment of hemorrhoids comprises, in accordance with the present invention, an anoscope and a hemorrhoid occlusion device, where the anoscope includes a hollow body closed at a distal end and at least partially open at a proximal end to define a longitudinal channel. The hollow body has a sidewall provided with a window spaced from at least the distal end. The hemorrhoid occlusion device includes an instrument shaft provided at a distal end with two jaws, at least one of the jaws including a C- or U-shaped clamping member movable alternately away and towards the other of the jaws for clamping and occluding hemorrhoidal tissues protruding through the window into the anoscope.

Applicant respectfully traverses the Examiner's rejection of claim 30, because one of ordinary skill in the art familiar with the teachings of Adams and Leisenring would not be motivated to provide the instrument assembly of claim 30. Neither Adams nor Leisenring suggests that the Adams resection system with its integrated endoscope could be used with the Leisenring speculum. An endoscope is not needed to perform a medical procedure with the Leisenring speculum. And an elongate flexible endoscope would impede any such procedure. (Conversely, an attempt to use the Leisenring speculum in a resection procedure as envisioned by Adams et al. would be futile. The Leisenring speculum would block the operation.) Moreover, there is no suggestion or motivation in Adams or Leisenring to use the stapling device of the Adams resection system apart from an endoscope. The stapling device is specially adapted for use with an endoscope and would be difficult if not impossible to use by itself with the Leisenring speculum. The stapling device disclosed by Adams would require significant modifications to enable use thereof with the Leisenring speculum. Such modifications are beyond the ordinary skill in the art.

Independent Claim 44 As set forth in previously presented claim 44, a surgical method utilizes (a) a hollow member having a peripheral wall provided with a window

and (b) a closure member slidably connectable to the hollow member for alternately covering and uncovering the window. The method comprises inserting, into a patient, the hollow member and the closure member, the closure member covering the window during the inserting of the hollow member and the closure member. Thereafter the cover member is shifted relative to the hollow member, thereby allowing tissues of the patient to protrude into the hollow member via the window. Subsequently, a portion of the protruding tissues is clamped between a pair of jaws. A tissue occlusion device in the jaws is actuated to effectuate a coupling of the protruding tissues. Then the jaws are opened to release the tissues. Thereafter the hollow member and the closure member are withdrawn from the patient, the tissues passing back through the window during this withdrawal process.

Claim 44 distinguishes over the prior art as represented by Adams and Leisenring for the reasons set forth above. One of ordinary skill in the art would not be motivated by Adams and Leisenring to practice applicant's method. Adams and Leisenring provide no teaching or suggestion to one of ordinary skill in the art to divorce the stapling device of Adams from the endoscope and use the stapling device by itself with the Leisenring speculum. Moreover, one of ordinary skill in the art would not contemplate using the resection system of Adams with the Leisenring speculum since the flexible endoscope is not only unnecessary but would also impede the use of the Leisenring speculum.

Independent Claim 45 New independent claim 45 includes essential limitations from claims 30 and distinguishes over Adams and Leisenring for the reasons discussed above. In addition, claim 45 recites a structural feature of the anoscope which does not appear in the Leisenring speculum and further distinguishes applicant's invention over Adams and Leisenring. That feature is the bulge in the sidewall of the anoscope body, the sidewall window being disposed particularly in the bulge or protrusion. As described in applicant's specification, the bulging portion of the anoscope serves as a retractor of collateral anal/rectal tissues. In addition, the protrusion creates

more workspace in the area of hemorrhoid. This design allows for better access to the base of the hemorrhoid, which is located in the submucosal layer close to the rectal muscle.

Neither Adams nor Leisenring discloses or suggests an instrument assembly comprising an anoscope and an occlusion device wherein the anoscope has a sidewall formed with a bulge or protrusion provided with a window.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

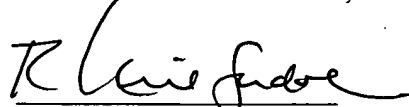
Conclusion

For the foregoing reasons, independent claims 20, 30, 44, and 45, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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